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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/771,259 | 02/02/2004 | Johan Georg Harmenberg | 1718-0214P | 2442 |

2292 7590 09/13/2005

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| EXAMINER |
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KRASS, FREDERICK F

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/771,259 | Applicant(s) HARMENBERG ET AL. | |
| | Examiner Frederick F. Krass | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,5,7-10,13-16,18,20,21,23-25,27-31,33-36 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,5,7-10,13-16,18,20,21,23-25,27-31,33-36 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. <u>9/1/05</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>A, B and C</u> . | 6) <input type="checkbox"/> Other: _____. |

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Previous Rejections

Unless specifically maintained infra, all previous rejections are withdrawn.

Claim Informalities

The following informality is noted and should be corrected in responding to this Office action:

Claim 24, last line, "134" should be changed to --- 13 ---

Reissue Oath is Defective

Claims 1-40 were rejected under 35 U.S.C. § 251 as relying upon a defective reissue oath/declaration.

This rejection is maintained.

A new oath is required which sets forth the alleged error requiring reissue with reasonable specificity, i.e., it must state why the claims are considered too broad over specifically identified prior art.

Indefiniteness Rejection

Claims 8-16, 24, 25 and 39 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained.

Amending the claims to recite "is contained" does nothing to address the substance of this rejection since the frame of reference for establishing the claimed percentages, e.g., "based on the weight of the pharmaceutical composition", continues to remain unclear.

Obviousness Rejection

1) Claims 1-4, 7, 13-21 and 23-40 were rejected under 35 U.S.C. 103(a) as being unpatentable over Levin (USP 5,656,301).

This rejection is maintained.

During the personal interview held with Applicant's representative on 9/1/05 (see the attached Interview Summary Form), language was agreed upon for a proposed amendment to overcome this rejection. This language would render moot the examiner's position that the LYCD component of Levin has not been shown to be excluded by the term "consisting essentially of". The proposed changes could not be entered by examiner's amendment since a new reissue oath has not yet been submitted. Accordingly, the rejection will be maintained subject to the understanding that Applicant will enter the proposed amendments in responding to this Office action, at which time a new reissue oath will also be submitted.

Using claim 2 for illustration purposes, the proposed amendments are as follows:

- a) Claim 2, second line, "consisting essentially of a synergistic" will be deleted and replaced by --- comprising, as sole active drug substances, a ---
- b) Claim 2, third line, immediately after "of" there will be inserted --- 1) ---
- c) Claim 2, third line, "active" will be deleted.
- d) Claim 2, seventh line, immediately after "and" there will be inserted --- 2) ---
- e) Claim 2, seventh line, "active" will be deleted.

f) Claim 2, penultimate line, "synergistic" will be deleted.

g) Claim 2, penultimate line, immediately after "effective" there will be inserted --- in treating said herpes infection ---

2) Claims 1-5, 7-10, 13-21 and 23-40 were rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (USP 4,902,678) in view of Underwood (USP 3,317,384).

This rejection is maintained.

Applicant's response to this rejection has apparently been omitted from the examiner's electronic ("E-DAN") file. Applicant discussed this rejection during the personal interview, and the examiner was persuaded by Applicant's position that the prior art would actually teach away from the addition of hydrocortisone to the prior art compositions. In order to be fully responsive, however, the examiner requests that Applicant restate his position in detail in responding to this Office action, in order to insure consideration on the record. The rejection will be maintained until such time as an adequate response is of record.

Review of Cited Prior Art

Applicant also expressed concern during the 9/1/05 interview that USP 6,514,980, and child cases thereof, might possibly pose an issue of interference. The examiner has carefully reviewed that patent and notes that no such issue would be raised because the patent never discloses, nor claims, the particular combination of acyclovir with hydrocortisone. No direction is provided for selecting that particular combination of agents, let alone in synergistic amounts.

Action is Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

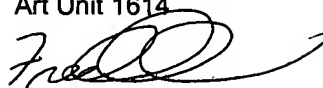
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Frederick Krass', with a stylized, flowing script.